IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	)	C.A. No.: 04-940-JJF **REDACTED PUBLIC VERSION**

PLAINTIFF THE PROCTER & GAMBLE COMPANY'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

Frederick L. Cottrell, III (#2555)
Steven J. Fineman (#4025)
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, DE 19899-0551
302-651-7700
Cottrell@rlf.com
Fineman@rlf.com
Attorneys for The Procter & Gamble Company

OF COUNSEL:
William F. Lee
David B. Bassett
Vinita Ferrera
Wilmer Cutler Pickering Hale and Dorr
60 State Street
Boston, MA 02109
617-526-6000

Dated: February 15, 2008

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

I. NATURE AND STAGE OF THE PROCEEDING

Plaintiff The Procter & Gamble Co. ("P&G") is the owner by assignment of United States Patent No. 5,583,122 (the "'122 patent") entitled "Pharmaceutical Compositions Containing Geminal Diphosphonates," which issued on December 10, 1996 and which expires on December 10, 2013. The commercial formulation of the compound risedronate sodium is covered by claims of the '122 patent. Risedronate sodium is manufactured and sold by P&G under the trade name Actonel®. Actonel® was approved by the FDA for 30 mg tablets on March 27, 1998; for 5 mg tablets on April 14, 2000; for 35 mg tablets on May 25, 2002; and for 75 mg tablets on April 16, 2007. The FDA's official publication of approved drugs (the "Orange Book") includes Actonel® in the above-identified dosages listed together with the '122 patent.

On July 2, 2004, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") sent notification to P&G, pursuant to 21 U.S.C. § 355(j)(2)(B), that it had filed Abbreviated New Drug Application ("ANDA") No. 77-132 with the Food and Drug Administration ("FDA"), seeking approval to market a generic version of Actonel® in the United States. In its notice, Teva informed P&G that its ANDA submission included a "paragraph IV certification," alleging that Teva's commercial manufacture, use, and sale of Teva's generic version of Actonel® would not infringe valid and enforceable claims of the '122 patent, and that the asserted claims of the '122 patent in this lawsuit are invalid.

Based on Teva's representations in its ANDA, P&G filed this action against Teva on August 13, 2004. (*See* Complaint, D.I. 1.) Following fact and expert discovery, the parties tried the case to this Court from November 6-8, 2006. Post-trial briefing was completed on January 27, 2007.

Prior to trial, Teva stipulated that its generic version of Actonel® infringes claims 4, 16, and 23 of the '122 patent. (*See* Stipulation and Order, dated Jan. 27, 2006, D.I. 63.) As a result,

the trial in this case was limited to the issue of the validity of the asserted claims. In particular, Teva alleged at trial that claims 4, 16, and 23 of the '122 patent are invalid as obvious under 35 U.S.C. § 103 and under the related theory of obviousness-type double patenting. P&G refuted these allegations by presenting evidence demonstrating that Teva had failed to meet its burden of proving by clear and convincing evidence that the '122 patent is invalid and that the '122 patent was not obvious. The parties submitted post-trial briefs and proposed findings of fact and conclusions of law on December 20, 2006 and reply briefs on January 26, 2007. Since post-trial briefing, the parties have also submitted two rounds of letters (in April and July 2007) to the Court regarding recent Federal Circuit decisions. A decision in the case has not yet been issued by the Court.

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Accordingly, pursuant to Fed. R. Civ. P. 65, P&G hereby moves this Court for a preliminary injunction preventing Teva from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, any drug product approved through ANDA No. 77-132, until the Court has issued a final judgment and ordered a permanent injunction in this action.

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P&G's motion is based on this Opening Brief, the accompanying Declaration of Daniel Hecht, the trial record, all of the pleadings and papers on file herein, and such other evidence as the Court may deem appropriate to consider.

II. SUMMARY OF ARGUMENT

1. The trial record demonstrates that there is a strong likelihood that P&G will succeed in defeating Teva's contention that the asserted claims of the '122 patent are invalid. At trial, Teva bore the burden of proving its obviousness theories by clear and convincing evidence. Teva did not come close to meeting that burden at trial, and the evidence presented by P&G affirmatively proved the validity of the '122 patent.

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4. The recognized public interest in promoting innovation by protecting patent rights will be advanced by granting P&G's requested injunction.

III. STATEMENT OF FACTS

The facts and arguments relating to the validity of the '122 patent claims are set forth fully in P&G's Proposed Findings of Fact (D.I. 99) and Post-Trial Brief and Proposed Conclusions of Law (D.I. 100), but are briefly summarized below for the Court's convenience.

A. The '122 Patent.

The '122 patent was filed on December 6, 1985. Drs. James Benedict and Christopher Perkins, both former P&G employees, are the named inventors. Claims 4, 16, and 23 of the '122 patent claim a bisphosphonate having the structure 2-(3-pyridyl)-1-hyrdoxyethane-1,1-diphosphonic acid ("3-pyr EHDP") (known as risedronate), pharmaceutical compositions of risedronate, and the use of risedronate in treating diseases associated with abnormal calcium and phosphate metabolism. (*See* Joint Trial Exhibit ("JTX") 1 (18:22-24, 20:54-56, 22:5-8).)

B. U.S. Patent No. 4,761,406.

U.S. Patent No. 4,761,406 (the '406 patent) was filed on June 6, 1985. Drs. Lawrence Flora and Benjamin Floyd, both former P&G employees, are the named inventors. The '406 patent claims a method for treatment of osteoporosis by administering a polyphosphonate for a specific period, followed by a specific period of rest, and repetition of this process. (*See* JTX 5.) In connection with the claimed method of treatment, the '406 patent identifies 36 bisphosphonates as examples of ones with which its dosing regimen may be used, including a bisphosphonate having the chemical structure 2-(2-pyridyl)-1-hyrdoxyethane-1,1-diphosphonic acid ("2-pyr EHDP"). 2-pyr EHDP is a compound that, while similar in chemical structure to

risedronate, was discovered by P&G to have very different safety and efficacy properties from risedronate. (*See id.* at 18:32-53.) Risedronate is not disclosed in the '406 patent.

C. Structure-Activity Relationships In Bisphosphonates.

It is a settled principle in the area of bisphosphonates that the relationship between the chemical structure of a compound and the biological activity and toxicity of that compound is highly unpredictable. (Trial Transcript ("Tr.")[2] at 382:15-383:18 (Bilezikian Dir.), 567:14-579:5 (McKenna Dir.), 838:7-12 (Miller Dir.).)

D. The Properties Of Risedronate.

Risedronate was found to be superior over hundreds of other compounds under study by P&G. (Tr. at 867:10-868:20 (Miller Dir.).) For example, risedronate was shown to have a safety-to-toxicity ratio ***ten times*** better than that of 2-pyr EHDP. (*Id.*) Risedronate has proven extremely effective in the treatment of osteoporosis. (*Id.* at 381:18-382:8 (Bilezikian Dir.).)

E. Long-Felt And Unmet Need For Treatments For Osteoporosis.

In the mid-1980s, there was a long-felt but unmet need for a compound of risedronate's therapeutic properties. (Tr. at 371:10-21 (Bilezikian Dir.).)

F. Commercial Success Of Risedronate.

Risedronate has been a resounding commercial success. (Tr. at 961:16-962:6, 970:18-971:7, 993:12-20 (Smith Dir.).)

G. Qualifications Of Teva's Expert Witness.

Teva's expert witness, Dr. Lenz, does not have experience in organo-phosphorous or bisphosphonate chemistry. (Trial Transcript ("Tr.") at 153-82 (Lenz Cross).) Dr. Lenz has never worked with bisphosphonates. (Tr. at 170 (Lenz Cross).)

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[2] The Trial Transcript may be found at Docket Index 89-91.

H. Qualifications Of P&G's Expert Witnesses.

Each of P&G's expert witnesses -- Drs. Bilezikian, McKenna, and Miller -- has extensive experience working with and conducting scientific studies on bisphosphonates. (Tr. at 341:1-12, 365:12-13 (Bilezikian Dir.); Tr. at 546:15-547:1, 548:15-23, 549:2-9 (McKenna Dir.); Tr. at 832:21 – 833:11, 836:3-23 (Miller Dir.).)

IV. ARGUMENT

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This Court has already heard the evidence in this case. This matter has been fully briefed and is before the Court to be decided on the merits. The duration of P&G's requested injunctive relief would likely be relatively short, and would impose minimal, if any, hardship on Teva, while serving the important public interest of protecting P&G's valuable patent rights.

A. The Standard For Preliminary Injunctive Relief.

Congress specifically contemplated the issuance of preliminary injunctive relief in situations such as this one. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(III) (providing that FDA approval of an ANDA shall not be made effective until the date of the court decision if "the court grants a preliminary injunction prohibiting the [ANDA] applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement").[3]

[3] *See also* 35 U.S.C. § 283 (stating that "[t]he several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable"); 35 U.S.C. § 271(e)(4)(B) (authorizing injunctive relief against an infringer "to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product" where patent infringement occurs through the submission of an ANDA for a drug claimed in a patent or the use of which is claimed in a patent).

The Federal Circuit considers the following factors in determining whether a preliminary injunction should issue against an infringer: (1) the reasonable likelihood of the patentee's success on the merits; (2) the likelihood of irreparable injury if the preliminary relief is not granted; (3) the balance of hardships to the parties; and (4) the impact on the public interest of the preliminary injunction. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988). No single factor is dispositive; the factors must instead be balanced against each other and against the form and magnitude of the relief sought. *Id.*; *Impax Labs., Inc. v. Aventis Pharmaceuticals, Inc.*, 235 F. Supp. 2d 390, 392 (D. Del. 2002). If, however, the patentee clearly establishes a reasonable likelihood of success (by making a clear showing of validity and infringement), it is entitled to a rebuttable presumption of irreparable harm. *Sanofi-Synthelabo v. Apotex, Inc.*, 488 F. Supp. 2d 317, 342 (S.D.N.Y. 2006) (finding that the patentee established a reasonable likelihood of success and benefited from the presumption of irreparable harm in granting preliminary injunction in the ANDA context), *aff'd*, 470 F.3d 1368 (Fed. Cir. 2006); *Polymer Techs. Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996); *Impax Labs.*, 235 F. Supp. 2d at 395-96.

B. Injunctive Relief Is Appropriate In This Case.

1. The Record Shows That Teva's Case For Invalidity Lacks Substantial Merit.

To show a reasonable likelihood of success on the merits, P&G need only show that the '122 patent is reasonably likely to withstand Teva's invalidity challenge based on obviousness and obviousness-type double patenting. Teva faces a burden of proving its obviousness theories by clear and convincing evidence -- a high and exacting standard. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996); 35 U.S.C. § 282. The Federal Circuit recently reiterated that this clear and convincing evidentiary burden is unshifting and that the burden of

proof remains on the party challenging the patent's validity throughout the litigation.[4] *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007) ("Since we must presume a patent valid, the patent challenger bears the burden of proving the factual elements of invalidity by clear and convincing evidence. That burden of proof never shifts to the patentee to prove validity"), *cert. denied*, 128 S. Ct. 110 (2007); *see also Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986) ("The presumption [of validity] remains intact and [the burden of proof remains] on the challenger throughout the litigation, and the clear and convincing standard does not change"). As set forth more fully in P&G's Post-Trial Brief (D.I. 100) and Post-Trial Reply Brief (D.I. 104), based on the evidence presented at trial by both sides, Teva does not have a reasonable likelihood of invalidating the '122 patent, particularly under this stringent burden.

First, Teva's "expert" witness, Dr. Lenz, lacked the qualifications to testify competently about the peculiarities of organo-phosphorous and bisphosphonate chemistry. (Tr. at 153-82 (Lenz Cross).) Notwithstanding Dr. Lenz's experience as a medicinal chemist, he has *never* worked with bisphosphonates. (Tr. at 170 (Lenz Cross).) The credibility of his opinion regarding the obviousness of risedronate in light of the '406 patent is questionable at best and does not support Teva's attempt to meet the clear and convincing evidence standard. Particularly in light of the contrary testimony from P&G's three highly qualified experts, Drs. Bilezikian, McKenna, and Miller, all of whom have conducted highly relevant studies of bisphosphonates, the arguments presented by Teva through Dr. Lenz carry little weight. (*See also* P&G's Post-Trial Brief, D.I. 100 at 16-18.)

[4] P&G rebutted Teva's contrary and incorrect statement of the law on this point in correspondence with the Court. (4/9/07 Letter from Frederick L. Cottrell, III to Hon. Joseph J. Farnan, D.I. 106.)

Beyond Dr. Lenz's lack of qualifications, the obviousness claims advanced by Teva lack substance and credibility. Teva bases its entire case upon disclosure of 2-pyr EHDP, a compound that, although structurally similar to risedronate, has never been developed for the treatment of any bone disease. To prove that the asserted claims are obvious, Teva must demonstrate not only that it would have been obvious to try modifying 2-pyr EHDP to form 3-pyr EHDP, but also that such a modification would have been reasonably likely to result in a successful compound. *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) ("The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art"); *N.V. Akzo v. E.I. DuPont de Nemours*, 810 F.2d 1148, 1151 (Fed. Cir. 1987) ("Of course, an 'obvious to try' standard is not a legitimate test of patentability"); *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495, 517 (D. Del. 2005) ("'obvious to try' does not equate with obviousness for purposes of Section 103") (Farnan, J.), *aff'd in part, rev'd in part*, 457 F.3d 1284 (Fed. Cir. 2006).

The Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), does not alter the analysis in this case. As stated by the Supreme Court:

> When there is a design need or market pressure to solve a problem and there are a ***finite number of identified, predictable solutions***, a person of ordinary skill has ***good reason*** to pursue the known options within his or her technical grasp. If this leads to the ***anticipated success***, it is likely the product not of innovation but of ordinary skill and common sense. In ***that*** instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR, 127 S. Ct. at 1742 (emphasis added). Thus, a person of ordinary skill in the art must still have had good reason to anticipate success, such as where there are a "finite number of

identified, predictable solutions" -- in other words a reasonable expectation of success -- to prove obviousness.

Indeed, applying *KSR* to a case involving a new pharmaceutical compound, the Federal Circuit expressly rejected an argument identical to the prime assertion in Teva's invalidity defense. Namely, the Federal Circuit found that the structural similarity of claimed and prior art compounds with substituted pyridyl rings is not, in itself, sufficient to establish prima facie obviousness. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359-60 (Fed. Cir. 2007). The Court held that its pre-*KSR* test for "obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*" and that "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Id.* at 1356-57.[5]

More particularly, in deciding that the claimed compound was not obvious in view of a structurally similar compound, the *Takeda* court concluded (a) "the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation," and (b) the closest prior art compound "exhibited negative properties that would have directed one of ordinary skill in the art away from that compound." *Takeda*, 492 F.3d at 1359. The same is true here. As the evidence at trial showed, the prior art disclosed an enormous number of bisphosphonates from which one could have selected a lead compound for further investigation. (Tr. at 611:19-615:12 (McKenna Dir.).) In addition, 2-pyr EHDP, the compound closest in structure to risedronate from among a broad selection of prior art compounds, was highly toxic and would, if anything, have taught away from risedronate. (Tr. at

[5] P&G discussed the *Takeda* case in greater length in its letter to the Court in July. (7/6/07 Letter from Frederick L. Cottrell, III to Hon. Joseph J. Farnan, D.I. 107.)

706:11-16 (McKenna Redir.); Tr. at 872:21-874:14 (Miller Dir.).) Teva's arguments simply fail to address these facts.

Without properly identifying a reason why researchers would be led to risedronate from the prior art compound, Teva's argument ignores the settled principle in the field of bisphosphonates that the relationship between chemical structure and biological activity and toxicity is highly unpredictable. (Tr. at 382:15-383:18 (Bilezikian Dir.), 567:14-579:5 (McKenna Dir.), 838:7-12 (Miller Dir.).) Because of this unpredictable structure-activity relationship, one of ordinary skill in the art would not (and could not) have reasonably expected that modifying 2-pyr EHDP to form 3-pyr EHDP would produce a compound that was both safe and effective for use in treating osteoporosis. (Tr. at 615:22-616:9, 627:19-23 (McKenna Dir.); Tr. at 870:4-871:9 (Miller Dir.).) Put another way (in light of *KSR*), given the unpredictability of potential solutions, a person of ordinary skill would not have had good reason to anticipate success. *See KSR*, 127 S. Ct. at 1742.

Teva also fails to rebut effectively the arguments regarding secondary considerations of nonobviousness, which overwhelmingly support the nonobviousness of the '122 patent. Particularly, P&G's experts and witnesses presented strong evidence of (1) risedronate's unexpected superiority over hundreds of other compounds under study by P&G, including evidence that risedronate has a ***ten times*** better safety to toxicity ratio than 2-pyr EHDP, (2) the long-felt but unmet need for a compound of risedronate's therapeutic properties, and (3) the resounding commercial success of risedronate. (Tr. at 371:10-21 (Bilezikian Dir.); Tr. at 867:10-868:20, 869:14-870:12 (Miller Dir.); Tr. at 961:16-962:6, 970:18-971:7, 993:12-20 (Smith Dir.).)

Finally, this Court has previously decided a case that is strikingly similar to the present one, in which Teva was again the defendant in an ANDA suit challenging the validity of a

bisphosphonate patent on obviousness grounds. In *Merck & Co. v. Teva Pharms. USA, Inc.*, 228 F. Supp. 2d 480 (D. Del. 2002) (Farnan, J.), this Court found that the relationship between structure and activity in the context of bisphosphonates is extremely unpredictable and held that Merck's patent claiming alendronate was not obvious in light of another bisphosphonate, pamidronate, that was similar in structure. Here again, in the context of the well known unpredictability of structure-activity relationships with bisphosphonates, Teva's invalidity attack on the '122 patent lacks merit.

2. P&G Will Suffer Severe And Irreparable Harm Absent Injunctive Relief.

The Federal Circuit has long held that "[i]rreparable harm is presumed when a clear showing of patent validity and infringement has been made." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001); *Polymer Techs.*, 103 F.3d at 973; *Sanofi-Synthelabo*, 488 F. Supp. 2d at 342 (finding that the patentee established a reasonable likelihood of success and benefited from the presumption of irreparable harm in granting preliminary injunction in the ANDA context), *aff'd*, 470 F.3d 1368 (Fed. Cir. 2006); *Impax Labs.*, 235 F. Supp. 2d at 395-96. Such a presumption derives in part from the limited length of the patent grant, given that this time period is not tolled during the pendency of litigation, and the passage of time can cause irreparable harm. *Amazon.com*, 239 F.3d at 1350.

There is some disagreement among the district courts as to whether this presumption survives the Supreme Court's decision in *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006). *Compare Quantronix, Inc. v. Data Trak Techs., Inc.*, Civil No. 07-1799 (DWF/AJB), 2008 WL 312810, at *8 (D. Minn. Feb. 1, 2008) ("Irreparable harm is presumed when a clear showing of patent validity and infringement has been made.... This presumption derives in part from the finite term of the patent grant, for patent expiration is not suspended during litigation,

and the passage of time can work irremediable harm.") and *Digene Corp. v. Ventana Medical Sys., Inc.*, 484 F. Supp. 2d 274, 279 (D. Del. 2007) ("A movant who clearly establishes a reasonable likelihood of success on the merits receives the benefit of the presumption of irreparable harm.") *with Sun Optics, Inc. v. FGX Int'l, Inc.*, Civil No. 07-137, 2007 WL 2228569, at *1 (D. Del. Aug. 2, 2007) (noting that allowing presumption of irreparable harm to attach on preliminary injunction application after showing of likelihood of success on merits appears inconsistent with *eBay*). While P&G believes its strong showing that the '122 patent is valid and infringed justifies a presumption of irreparable harm, the evidence supports a finding of irreparable harm even absent such a presumption.

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3. **The Balance of Hardships Sharply Favors P&G.**

The balance of hardships to the parties strongly favors P&G's requested injunctive relief.

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On the other hand, granting injunctive relief will leave Teva in precisely the same position that it is in now. *See Impax Labs., Inc.*, 235 F. Supp. 2d at 396 (finding that "granting the Motion for Preliminary Injunction will cause Impax only minimal hardship since doing so will leave Impax in the same position as it was in before the injunction was granted, *i.e.*, excluded from the riluzole market"). Even if the Court ultimately finds the '122 patent to be invalid, the short period of time during which Teva would be affected by the injunction limits any hardship it may suffer. *See id.* Finally, even if Teva loses sales while an injunction is in place, this cannot outweigh the potential harm to P&G without the injunction. "Simply put, an alleged infringer's loss of market share and customer relationships, without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct." *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005).

4. **The Public Interest Favors Injunctive Relief.**

Finally, granting injunctive relief in this case will serve the public interest in enforcing patent rights and encouraging innovation. *See Abbott Labs.*, 849 F.2d at 1458 (affirming district court's finding that the public interest in enforcing patent rights outweighed any other public interest considerations as to all but two of defendants' products). Teva cannot rely on the lower price of generic pharmaceuticals to overcome these considerations:

> [W]hile the statutory framework under which [Teva] filed its ANDA does seek to make low cost generic drugs available to the public, it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents.

Pfizer, 429 F.3d at 1382. Moreover, the Federal Circuit has held that the public interest in the enforcement of the patent system (thereby encouraging the development of new drugs) outweighs the interest of the public in having generic drugs. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383-85 (Fed. Cir. 2006) (agreeing that the district court did not err in finding that "the interest in encouraging and incentivizing pharmaceutical research and development" outweighed the public interests advanced by the generic drug manufacturer); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985) ("[E]ncouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude").

Granting injunctive relief will additionally serve the public interest in judicial efficiency.

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On the other hand, this Court has already heard trial testimony,

weighed evidence, considered the parties' post-trial briefs, and is in a position to render its decision in the near term. The granting of injunctive relief during the time pending such a decision will thus significantly conserve judicial resources.

V. CONCLUSION

Based on the foregoing, P&G respectfully requests that the Court set a schedule to consider and issue a preliminary injunction (before May 1, 2008) preventing Teva from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of any drug product approved through ANDA No. 77-132, pending the resolution of this lawsuit.

Frederick L. Cottrell, III (#2555)
Steven J. Fineman (#4025)
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, DE 19899-0551
302-651-7700
Cottrell@rlf.com
Fineman@rlf.com
Attorneys for The Procter & Gamble Company

OF COUNSEL:
William F. Lee
David B. Bassett
Vinita Ferrera
Wilmer Cutler Pickering Hale and Dorr
60 State Street
Boston, MA 02109
617-526-6000

Dated: February 15, 2008

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on February 15, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

Karen L. Pascale, Esquire
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
P. O. Box 391
Wilmington, DE 19899-0391

I hereby certify that on February 15, 2008, I have sent by Electronic Mail, the foregoing document to the following non-registered participants:

James Galbraith
Maria Luisa Palmese
Anthony Pfeffer
Kenyon & Kenyon
One Broadway
New York, NY 10004

Steven J. Fineman (#4025)
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, Delaware 19899
(302) 651-7700
Fineman@rlf.com

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

Karen L. Pascale, Esquire
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
P. O. Box 391
Wilmington, DE 19899-0391

I hereby certify that on February 25, 2008, I have sent by Electronic Mail, the foregoing document to the following non-registered participants:

James Galbraith
Maria Luisa Palmese
Anthony Pfeffer
Kenyon & Kenyon
One Broadway
New York, NY 10004

Steven J. Fineman (#4025)
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, Delaware 19899
(302) 651-7700
Fineman@rlf.com